United States
Department of
Agriculture

Food Safety
and Inspection
Service

April 1 thru
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Compilation of Meat and Poultry Inspection Issuances

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This publication covers issuances published during the period April 1 through 30, 1993.

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D. C.

FSIS NOTICE

18-93 | 4-14-93

SUPPLEMENTAL SPLIT SAMPLING INSTRUCTIONS

I. PURPOSE

This notice instructs inspectors to record a special Performance-Based Inspection System (PBIS) task when selecting and mailing split samples to the FSIS Technical Support Laboratory (TSL). Inspectors currently submit split samples but do not record performance of the task in PBIS. The special task code is a unique code not listed in the Inspection System Guide (ISG) and is being used as an interim measure.

II. POLICY/BACKGROUND

The split sampling procedure is a sampling method used to monitor accredited laboratory (AL) procedures. A split sample is an official sample divided into two duplicate portions. One portion is analyzed by the AL for official regulatory purposes and the other portion by a TSL for monitoring purposes. Science and Technology uses split samples to monitor AL performance. This notice informs inspectors of their new responsibilities when performing this task.

III. INSPECTOR INSTRUCTIONS WHEN PERFORMING SPECIAL TASK CODE 98Z01a2

A. When an establishment requests that an inspector use an accredited laboratory in lieu of an FSIS TSL for analyzing moisture, protein, fat and salt content in meat and poultry products, the inspector should, after accumulating five split samples for monitoring AL performance,:

1. randomly select and send one of the five split samples to the TSL,

DISTRIBUTION: Inspec. Offices, T/A Inspectors, Plant Mgt., T/A Plant Mgt., ABB, PRD, AID

NOTICE EXPIRES:

OPI: S&T/PPID

2. write task code 98Z01a2, including the 80-character task description (Select/process/mail split samples to TSL) on FSIS Form 8800-2, Inspector Assignment Schedule, and place an "X" in the "Acc" column and

3. return the remaining four samples to establishment management.

B. The inspector should repeat the steps in paragraphs A.1.-3. above each time five split samples are accumulated when an establishment requests that the inspector use an accredited laboratory in lieu of an FSIS TSL for analyzing moisture, protein, fat and salt content in meat and poultry products.

C. The inspector should continue utilizing this special task code until instructed otherwise.

D. The following example illustrates how the special task code appears in ISG format:

Task Code	Compliance Standards	Reference	Task Description
98Z01a2	Split sampling procedures are followed when sending split samples to TSL.	Manual 23.1; FSIS Notice	After accumulating five split samples, select, process, and mail one split sample to TSL as directed by FSIS Notice

E. The following example illustrates how the task code and 80-character task description should appear on the Inspector Assignment Schedule when documenting performance of this special task code:

80-CHARACTER TASK DESCRIPTION	
98Z01a2	Select/process/mail split samples to TSL

F. If additional guidance is needed, the inspector should contact his or her immediate supervisor.

Deputy Administrator
Inspection Operations

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D.C.

FSIS DIRECTIVE

7320.1 | 4-27-93

Treatment of Certain Meat and Poultry Products Containing Pork to Destroy Trichinae

I. PURPOSE

This directive clarifies the regulations on the treatment of sausage and sausage-like products for the destruction of trichinae.

II. [RESERVED]

III. [RESERVED]

IV. REFERENCES

MPI Regulations, Sections 318.10 and 381.147

V. BACKGROUND

A. Section 318.10(a) of the MPI Regulations provides that some forms of fresh pork products are usually well cooked in the home or elsewhere before they are consumed. Therefore, such products do not require treatment for the destruction of trichinae that may be present in the pork component of the products.

B. Sections 318.10(a)(2) and 381.147(d)(2) of the MPI Regulations provide that pork found free of trichinae using various tests prescribed in the regulations is not required to be treated for the destruction of trichinae.

DISTRIBUTION: Inspection Offices, T/A Inspectors, Plant Mgt., T/A Plant Mgt., TRA, ABB, PRD, AID
OPI: S&T/PPID

C. Pork may be an ingredient in meat and poultry products. In some of these products, the presence of pork may not be readily apparent, and usual cooking procedures may not destroy trichina larvae that may infest the pork. To protect consumers, sections 318.10(b) and 381.147(d) of the MPI Regulations require that certain pork and pork-containing products (including mixtures of pork and other meat or poultry products) other than those containing pork tested as described in Paragraph V., B. above, be treated to destroy trichinae or consist of pork that has been treated to destroy trichinae.

D. The regulations are not precise regarding which mixtures of pork and other meat or poultry products require treatment to destroy trichinae. The regulations state that such mixtures must be treated for trichina when the Administrator determines, upon prior label review or upon product evaluation, that the product may be eaten rare or without thorough cooking because of its appearance or other reasons. A number of such determinations have been made under this provision.

VI. SAUSAGE AND SAUSAGE-LIKE PRODUCTS CONTAINING PORK AND OTHER MEAT OR POULTRY PRODUCTS THAT HAVE BEEN FOUND TO NOT REQUIRE TREATMENT TO DESTROY TRICHINAE

A. Products with a diameter of 1 inch or less. Such sausage and sausage-like products would normally be adequately cooked by the consumer to destroy trichinae that may be present in the pork.

B. Products of any size that are stuffed into plastic or other inedible casings, often called chubs, and labeled with the word "pork" in the product name. These products are designed to be sliced and cooked as patties or removed from the casing and added to other products, such as meat loaf. In both cases, normal cooking, based on the clear information that pork is contained in the product, would ensure the destruction of trichinae.

VII. SAUSAGE AND SAUSAGE-LIKE PRODUCTS CONTAINING PORK AND OTHER MEAT OR POULTRY PRODUCTS THAT HAVE BEEN FOUND TO REQUIRE TRICHINA TREATMENT

A. Products with a diameter of over 1 inch, except as packaged and labeled in Paragraph VI. B. above.

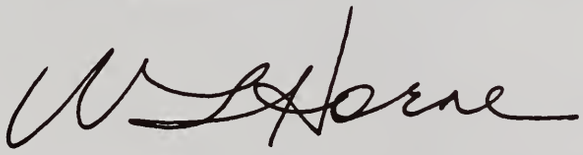
B. Products containing wine or cure.

C. Products that receive a treatment, such as cooking or smoking, which makes it difficult to determine whether the products have been adequately cooked to destroy trichinae.

D. Products containing red peppers, paprika, excess sugar, or any other ingredient which imparts coloring to the raw products or influences the appearance during cooking, thereby making it difficult to determine whether the products have been adequately cooked to destroy trichinae.

E. Products containing unusual ingredients, such as eggs or tomatoes, which make it difficult to determine whether the products have been adequately cooked to destroy trichinae.

For the sausage and sausage-like products described in Paragraph VII. C, D, and E, the establishment or inspector may find it particularly difficult to judge whether treatment to destroy trichinae is necessary. In these cases, the establishment may call the Processed Products Inspection Division at (202) 720-2006 for instructions regarding submitting frozen product samples for a final determination.



Deputy Administrator
Inspection Operations

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D.C.

FSIS DIRECTIVE

8100.1
Rev. 1

4-2-93

PLANNED COMPLIANCE PROGRAM

I. PURPOSE

This directive describes the Planned Compliance Program and identifies responsibilities to:

A. Prevent unsound meat or poultry products from entering human food channels.

B. Assure compliance with the Federal Meat Inspection Act and the Poultry Products Inspection Act, and

C. Obtain and maintain current data on persons or firms engaged as commercial handlers of meat and poultry products.

II. CANCELLATION

FSIS Directive 8100.1, dated 8/5/83.

III. REASON FOR REISSUANCE

This directive has been rewritten in its entirety to update instructions and organizational references.

IV. REFERENCES

Federal Meat Inspection Act
Poultry Products Inspection Act

V. ABBREVIATIONS AND FORM

The following abbreviations appear throughout this directive:

FMIA Federal Meat Inspection Act
OIG Office of the Inspector General
PCP Planned Compliance Program
PPIA Poultry Products Inspection Act

FSIS Form 8000-8, Review and Compliance Record, dated 12/92 (formerly FSIS Form 8000-8, dated 4/92)

DISTRIBUTION: Inspection Offices, T/A Inspectors, Plant Mgt., T/A Plant Mgt., TRA, ABB, PRD, AID

OPI: RP/CP

VI. POLICY

The PCP, a principal operating program of the Compliance Program, Regulatory Programs, monitors persons and firms dealing in all phases of the distribution chain of meat and poultry products, including handlers of dead, dying, diseased, or disabled livestock or poultry.

VII. COMPONENTS OF THE PLANNED COMPLIANCE PROGRAM

The PCP consists of:

A. A computer database that contains pertinent information with respect to the person or firm assigned a risk category number (Paragraph IX. of this directive). The database is maintained in the Evaluation and Enforcement Division, Compliance Program.

B. Periodic reports, with respect to the person or firm, made by Compliance Program personnel. Reports are made on FSIS Form 8000-8 (see Attachment), and are submitted to and maintained in the Evaluation and Enforcement Division, Compliance Program.

C. A review scheduling system that controls the frequency of compliance reviews based on the Agency's record (in the computer database) of violations and/or concerns about a person or firm. Reviews are scheduled on the basis of the "risk category" number assigned to the person or firm.

VIII. FREQUENCY OF REVIEWS AND RISK CATEGORIES UNDER THE PLANNED COMPLIANCE PROGRAM

A. Compliance reviews shall be made as indicated below for each category:

Categories

Risk category 1 - quarterly
Risk category 2 - semiannually
Risk category 3 - annually
Risk category 9 - indefinite

B. **Deviation from frequency of compliance reviews**. The Compliance Officer or the Officer in Charge may schedule more frequent reviews than are set forth above as deemed necessary to assure compliance.

IX. CRITERIA FOR ASSIGNMENT OF RISK CATEGORY NUMBERS

A. The general policy with respect to criteria is to assign a person or firm to the appropriate risk category, based on the specific criteria given below for each category:

1. **RISK CATEGORY 1**

a. Indications that the person or firm is presently violating provisions of the FMIA or PPIA; or

b. Indications that the person or firm is presently placing unsound meat, meat food products, poultry, or poultry products into human food channels (absolute proof is not necessary); or

c. The person or firm is engaged in an activity which particularly lends itself to the placing of unsound meat, meat food products, poultry, or poultry products into human food channels.

2. **RISK CATEGORY 2**

a. Violations(s) of the FMIA or PPIA by the person or firm within the past 12 months (as established by a submitted violation report or a completed OIG investigation report); or

b. Indications that the person or firm has placed unsound meat, meat food products, poultry, or poultry products into human food channels within the past 12 months (absolute proof is not necessary); or

c. The past operations of the person or firm demonstrate that they constitute a constant or intermittent risk in regard to either of the above conditions listed in Paragraph IX. A.2.a. and b.

3. **RISK CATEGORY 3**

a. Violation(s) of the FMIA or PPIA by the person or firm within the past 24 months (as established by a submitted violation report or a completed OIG investigation report); or

b. Indications that the person or firm has placed unsound meat, meat food products, poultry, or poultry products into human food channels within the past 24 months (absolute proof is not necessary).

4. **RISK CATEGORY 9**

a. Indications that the person or firm should be retired from active scheduling under the following circumstances:

(1) A permanent closing of business operations by the firm; or

(2) Death of the person; or

(3) A complete change in the person's or firm's business activities which precludes any handling of meat, meat food products, poultry, or poultry products; or

(4) Active scheduling is determined nonproductive by the Officer in Charge.

B. **Deviation from criteria**. The Compliance Officer may deviate from the criteria set forth in the risk categories whenever it is believed that such action is necessary. Such action shall be: (1) Documented on FSIS Form 8000-8, giving the reasons for such deviation, and (2) Approved by the Officer in Charge.

Margaret O'K. Glavin

Deputy Administrator
Regulatory Programs

Attachment
FSIS Form 8000-8, Review and Compliance Record

REVIEW AND COMPLIANCE RECORD

(See PCP Guidelines for Completion of Blocks)

NAME OF FIRM

PART I

NATURE OF ACTION

A = Add New Firm
BC = Update based upon review Parts I, II & III
C = Change Form, Part I, II or III
D = Delete Form

SCO'S INITIALS	AREA	CONTROL NUMBER (8 characters)	STATUS	AREA ASSIGN CODE	DATE OF THIS REVIEW (MM DD YY)

PART II

FIRM NAME (No more than 30 characters entered)	FEDERAL EST NO (ADP Format-8 characters)	POULTRY EST NO (ADP Format-7 characters) P

PREVIOUS FIRM NAME (If applicable) (No more than 30 characters entered) — STATE EST NO. (5 Characters) S

☐ AKA ☐ DBA — FIRM NAME (If applicable) (No more than 30 characters entered)

STREET ADDRESS OR R F D NO (No more than 26 characters entered) — CITY (No more than 20 characters entered)

STATE ABBREVIATION	ZIP CODE (No more than 10 digits w/ hyphen)	RISK CATEGORY 1 2 3 4 5 9	TYPE OF PRODUCT M = Meat P = Poultry B = Meat and Poultry
	—		

TYPE OF BUSINESS (Codes* in order of predominance)	INSPECTION PROGRAM N = None F = Federal S = State T = Talmadge-Aiken	TOLERANCE ESTABLISHMENT N = None P = Partial T = Total	GRADING CODE N = None F = Federal	IF VIOLATION OF FMIA AND/OR PPIA WAS FOUND, ENTER CODE

PART III

MANAGING OFFICIAL NAME 1 (No more than 30 characters entered) — MANAGING OFFICIAL NAME 2 (No more than 30 characters entered)

ADDRESS 1 (No more than 60 characters entered - 30 per line) — ADDRESS 2 (No more than 60 characters entered - 30 per line)

CASE NUMBER	PRED. CODE	PRED DATE	NO OF VIOL	VIOLATION DATE	CASE DATE	LOW ISSUE DATE

SOURCE(S) OF INFORMATION, ADDITIONAL REMARKS, AND OTHER PERTINENT INFORMATION (Include names and addresses where appropriate)

AREA OFFICE	NAME OF OFFICER	BADGE NO

*CODE: 01 = Processor; 02 = Distributor; 03 = Renderer; 04 = Broker; 05 = (4-D); 06 = Retailer; 07 = Transporter; 08 = Custom; 09 = Restaurant; 10 = Abattoir; 11 = Animal Food; 12 = Warehouse; 13 = Salvage; 14 = Miscellaneous

FSIS FORM 8000-8 (12/92) REPLACES FSIS FORM 8000-8 (4/92), WHICH MAY BE USED UNTIL EXHAUSTED

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D.C.

FSIS DIRECTIVE

10,130.1
Rev. 3

4-30-93

UNIDENTIFIED ANALYTICAL RESPONSES (UARs)

I. PURPOSE

This directive prescribes FSIS's policy for monitoring, identifying and reporting of UARs that occur in the residue program.

II. CANCELLATION

FSIS Directive 10,130.1, Rev. 2, dated 5-22-90.

III. REASONS FOR REISSUANCE

A. This revision expands the previous UAR directive to all residue analyses carried out by the TSLs or accredited laboratories. Furthermore, this directive places additional responsibility at the laboratory level for deciding if a UAR should be further investigated.

B. Paragraph IX. has been added to provide guidelines for the disposition of a product that contains a UAR.

C. The reporting requirement for the UAR Committee has been changed from monthly to quarterly because fewer UARs are currently being seen than in past years.

D. The names of certain program areas, as well as the analytical responsibilities of the TSLs, have changed subsequent to the 1990 directive. Further, the reference to the Western Laboratory in the directive of 1990 is no longer appropriate.

E. Because of the extensive changes to this directive, it has been rewritten in its entirety.

IV. REFERENCE

Analytical Chemistry Laboratory Guidebook - Winter 1991

DISTRIBUTION: Inspection Offices, T/A Insp. Plant Mgmt., T/A Plant Mgmt., TRA, ABB, PRD, AID

OPI: S&T/REPD

V. ABBREVIATIONS

The following abbreviations are used in this directive:

CD	Chemistry Division
CES	Compound Evaluation System
IO	Inspection Operations
MARCIS	Microbiological and Residue Computer Information System
REPD	Residue Evaluation and Planning Division
ROS	Residue Operations Staff
S&T	Science and Technology
TSL	Technical Services Laboratory
UAR(s)	Unidentified Analytical Response(s)
UMA	UAR Method Addendum

VI. POLICY

This directive identifies FSIS's system for monitoring UARs. The TSLs will report UARs as they are found in official samples to the Chief, Evaluation Branch, REPD, and the Director, CD, by entering the appropriate data into the MARCIS. The TSLs, REPD, and CD will evaluate UAR data for frequency of occurrence, product type, geographical source, Relative Concentration or any other factor which may determine the reasons for unknown detector responses. Additional sampling may be carried out by the Epidemiology and Emergency Programs Staff, IO, and further analyses may be performed if data evaluations indicate that they are necessary. When the identity of a UAR is determined, a CES evaluation of the compound or another means of assessing risk may be undertaken.

VII. DEFINITIONS

A. UAR. A UAR is an analytical response caused by a compound with chromatographic properties different from those of known reference standards and reagents; this can include endogenous components from tissue matrices. The majority of these responses are insignificant and vary among different chemical methodologies and tissue matrices.

B. UAR Committee. A committee at a TSL that is responsible for reviewing UAR data and making recommendations to REPD on continued work on the UAR. The committee will include the analyst, the supervisor for the laboratory section responsible for that method and the Chemist-in-Charge for Regulatory Chemistry.

VIII. EVALUATION PROCEDURES AND RESPONSIBILITIES

This paragraph describes the general procedures to be used by S&T personnel to evaluate and report UARs.

A. Recognition and Evaluation of UARs.

1. The individual TSL UAR committees will evaluate available information for each UAR finding and make recommendations to REPD and other interested divisions. In making the decision to pursue identification of the UAR, the UAR committee will follow guidelines specified in the Analytical Chemistry Laboratory Guidebook for that specific method. Each set of guidelines will be termed a "UAR method addendum" and will appear in the Guidebook as an attachment to the published method.

2. UMAs will be developed as needed for methods that are in current use in the National Residue Program. Each UMA will be written by the TSL that performs the method in consultation with the Quality Systems Branch, CD. Each UMA will contain specific procedures for entering data into MARCIS. The general format each UMA will follow is specified in Paragraph XI. of this directive.

3. It is expected that appended UMAs to each in-use Guidebook method will not be available until July 1994. Therefore, until a UMA has been developed for a method, the following general guidelines will be employed to determine if it is justified to expend resources to identify a UAR. The TSL will do the following:

a. Proceed with identification only if the instrument response peak is of significant size; 3x the Lowest Reliable Quantitation of the method's reference compound is recommended as a general guideline. Determine the Relative Retention Time or Relative Retardation Factor and, where feasible, the Relative Concentration.

b. Use appropriate analytical methods (this will typically be mass spectrometry) to determine if the UAR is likely to correspond to a compound in the same class as that for which the method is designed. For example, if a UAR is found in a sulfonamide method, attempt to determine if the UAR is likely to be a sulfonamide.

c. If mass spectrometry, or some other informative analytical method, indicates that the compound appears to belong to the same class as that for which the method is designed, attempts will continue to be made to identify the compound. If the compound does not appear to belong to the same class as that for which the method is designed, significant additional resources should not be expended to attempt identification unless the compound appears to contain a halogen, aromatic amine or aromatic nitro group. Resources will not be expended to identify the compound if there is good reason to believe it is endogenous. If a compound is present in virtually all samples analyzed from a variety of sources, then it is likely to be endogenous. In a new method, at least 300 samples, from a variety of sources, should be analyzed before making a judgment that a compound is endogenous.

d. Following consultation with the TSL, REPD will recommend whether further identification of the UAR should be conducted by either the TSL, the Food and Drug Administration, or an academic or private laboratory working under government contract. REPD may also recommend that no further work be conducted to identify the UAR.

B. **UAR Data Entry, Report Generation and Report Distribution.**

1. After the TSL UAR committee agrees that the response is a UAR, the TSL should telecopy a completed copy of the agency sample form to the Chief, Evaluation Branch, REPD, and the Director, CD. When available, forward a copy of the completed analysis, all reports and information, including mass spectral data, to the above individuals by the next working day.

2. REPD and the Statistics and Data Systems Division are responsible for jointly reviewing the UAR data in MARCIS on a quarterly basis. The information in MARCIS will contain the following:

a. Relative Retention Time, Relative Retardation Factor and Relative Concentration (relative to the compound of interest on a method-specific basis), and Electron Impact Mass Spectrometry and Chemical Ionization Mass Spectrometry data, if applicable.

b. Species or product type.

c. Laboratory where analyzed.

d. Geographic area or county (identify imports in MARCIS).

e. Test method used (add to comment section in MARCIS).

f. Form number.

g. Internal laboratory sample number.

h. Identity of the UAR, when determined.

3. International Programs and Residue Operations Staff, IO, will receive a quarterly printout of the UAR data in MARCIS summarizing outstanding UARs.

C. **Custody of Data and Samples.** The TSLs will be responsible for the following activities:

1. Maintaining properly labeled chromatogram(s), mass spectrogram(s) and UAR data profiles of the sample analysis in the laboratory files.

2. Maintaining a properly labeled tissue sample in frozen storage for not less than 6 months.

D. **UAR Quarterly Evaluation.** REPD, CD, and the TSLs will jointly evaluate the UAR data quarterly and make either of the following recommendations to the Deputy Administrator, S&T:

1. Further analytical work should be conducted in a TSL on samples exhibiting similar data profiles to provide specific chemical identification for recurring UARs, or

2. Further analytical work should be contracted with the Food and Drug Administration or an academic or private laboratory working under government contract.

E. **Program Action.** Once a UAR has been identified, the following actions may be initiated for future regulatory consideration:

1. A CES assessment by REPD.

2. A toxicologic evaluation by REPD.

3. An analytical method evaluation by CD.

4. An epidemiologic investigation by the Epidemiology and Emergency Programs Staff, IO.

5. Use of resources from other public health organizations for compound assessment.

IX. DISPOSITION OF A PRODUCT WHICH CONTAINS A UAR

If a product is being held pending laboratory analysis and a UAR is found but not identified and the product is not otherwise condemned, the following procedure should be followed:

A. The TSL will notify the Regional Residue Staff Officer of this situation within the established laboratory analysis turnaround time.

B. The Regional Residue Officer will consult with ROS regarding the disposition of this product.

X. ANALYSIS AND REPORTING PROCEDURES OF UARs BY AN FSIS CONTRACT LABORATORY

When an FSIS contract laboratory detects a UAR, the laboratory will forward all relevant information and a portion of the sample to the TSL for which the contract laboratory was performing the analysis.

XI. GENERAL FORMAT FOR THE UMA

Each UMA will be specific for a given method and will address method characteristics and the significance of the UAR.

A. The first section of the UMA will evaluate method characteristics, including:

1. Cleanup specificity,

2. Detection specificity,

3. Portion of the chromatogram that it is relevant to examine (isolation of the questionable area),

4. Special considerations for tissue, species, and product type, and

5. Method status (e.g., is the method validated).

B. The second section of the UMA will evaluate the UAR itself. The following criteria should be used to assess the significance of the UAR:

1. Peak response size,

2. Peak location, and

3. Frequency of occurrence.

C. Routine analytical procedures to be followed when a significant UAR is found:

1. Reinject or reanalyze the sample.

2. The TSL UAR committee will review and recommend analytical follow-up (e.g., mass spectrometry, atomic emission spectroscopy, nuclear magnetic resonance, or analysis on a second chromatography column).

D. Reporting procedures.

1. Appropriate MARCIS code numbers will be contained in each addendum.

2. TSL UAR committee will report findings in MARCIS to REPD.

Deputy Administrator
Science and Technology

*U.S. G.P.O.:1993-341-645:80013/FSIS